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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 7

Complete if Known

Application Number	09/776,936
Filing Date	December 22, 1998
First Named Inventor	Scott Miller
Group Art Unit	1621
Examiner Name	Kumar, Shailendra
Attorney Docket Number	BAYER-0006-P01

U.S. PATENT DOCUMENTS

Examiner Initials ¹	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
	A1	4,546,191		Nishiyama et al.	10-08-1985
	A2	6,380,218		Marafat et al.	04-03-2002
	A3	6,525,046		Cirillo et al.	02-25-2003
	A4	6,500,863		Jin et al.	12-31-2002
	A5	6,040,339		Yoshida et al.	03-21-2000
	A6	6,150,415		Hammock et al.	11-21-2000
	A7	6,178,399		Takebayashi et al.	01-23-2001
	A8	6,187,799		Wood et al.	02-13-2001
	A9	7,625,915		Dumas et al.	12-01-2002

FOREIGN PATENT DOCUMENTS

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		Office ⁴	Number ⁴	Kind Code ² (if known)				
	B1	DE	3529247	A1	Bayer AG	11-20-1986		A9
	B2	WO	90/02112		The Nutrasweet Company	03-08-1990		
	B3	EP	0690344	A1	Konica Corporation	01-03-1996		
	B4	WO	97/09973	A1	The Regents Of The University Of California	3-20-1997		
	B5	WO	98/20868	A1	The Picower Institute of Medical Research	05-22-1998		
	B6	WO	98/45268		Pfizer Products, Inc.	10-15-1998		
	B7	WO	99/28305	A1	E. I. Du Pont de Nemours & Co.	06-10-1999		
	B8	WO	00/43366	A1	Kirin Beer Kabushiki Kaisha	07-27-2000		A9
	B9	WO	00/56331	A1	Vertex Pharmaceuticals, Inc.	09-28-2000		
	B10	WO	02/14331		The University of Kansas	02-21-2002		
	B11	WO	02/062763	A2	Bayer Corporation	8-15-2002		


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	B12	WO	02/083628	A1	Boehringer Ingelheim Pharmaceuticals, Inc.	10-24-2002		
	B13	WO	02/085857	A2	Bayer Corporation	10-31-2002		
	B14	WO	02/085859	A1	Bayer Corporation	10-31-2002		
	B15	WO	02/092576	A1	Boehringer Ingelheim Pharmaceuticals Inc.	11-21-2002		
	B16	WO	03/099771	A2	Novartis AG	12-04-2003		

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	C1	ADJEI et al., "A phase I study of BAY 43-9006 and gefitinib in patients with refractory or recurrent non-small-cell lung cancer (NSCLC)," Meeting: 2005 ASCO Annual Meeting, Category: Developmental Therapeutics: Molecular Therapeutics, Subcategory: Antiangiogenic or Antimetastatic agents, Abstract No. 4510	
	C2	AHAMD et al., "Kinase inhibition with BAY 43-9006 in renal cell carcinoma," Clinical Cancer Research, Vol. 10, 6388s-6392s, 15 Sept. 2004	
	C3	AUCLAIR, et al., "BAY 43-9006 (Sorafenib) is a potent inhibitor of FLT3 tyrosine kinase signaling and proliferation in AML cells," 96th Annual Meeting, April 16-20, 2005, Anaheim/Orange County, CA	
	C4	BANKSTON, D. ET AL. "A Scaleable Synthesis of BAY 43-9006: A Potent Raf Kinase Inhibitor for the Treatment of Cancer" Organic Proc. Research Development, 2002, Vol. 6, No. 6, pp. 777-781	
	C5	BLANCO, "p38 MAPK signaling cascades: ancient roles and new functions," Bioassays, 22:637-645, 2000	
	C6	BOLLAG, G ET AL., "Raf pathway inhibitors in oncology" Curr. Opin. Invest. Drugs 2003, 4(12), 1436-1441.	
	C7	CAMPBELL et al., "Increasing complexity of Ras signaling," <i>Oncogene</i> , (1998) 17, 1395-1413	
	C8	CARTER et al., "Anti-tumor efficacy of the orally active raf kinase inhibitor BAY 43-9006 in human tumor xenograft models," #4954, XP-001145482	
	C9	CHANG et al., "BAY 43-9006 (Sorafenib) inhibitors ectopic (s.c.) and orthotopic growth of a murine model of renal adenocarcinoma (Renca) predominantly through inhibition of tumor angiogenesis," 96 th Annual Meeting, April 16-20, 2005, Anaheim/Orange County, CA	

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	C10	CLARK et al., "Safety and pharmacokinetics of the dual action raf kinase and vascular endothelial growth factor receptor inhibitor, BAY 43-9006, in patients with advanced, refractory solid tumors," <i>Clin. Cancer Res.</i> , 2005:11(15), 1 August 2005, 5472-5480	
	C11	DANSON et al., "Improving outcomes in advanced malignant melanoma," <i>Drugs</i> , 2005, 65(6):733-743	
	C12	DEGREDELLE, H: "Activity of the Raf kinase inhibitor BAY 43-9006 in patients with advanced solid tumors" <i>Clin. Colorectal Cancer</i> 2003, 3(1), 16-18.	
	C13	DUMAS, J. "Protein Kinase Inhibitors from the Urea Class" <i>Curr. Opin. Drug Discov. Dev.</i> 2002, 5(5), 715-724.	
	C14	DUMAS, J. ET AL., "Recent Developments in the Discovery of Protein Kinase Inhibitors from the Urea Class" <i>Current Opinion Drug Discovery Development</i> 2004, Vol. 7 No. 5, pp. 600-616.	
	C15	DUMAS, J. ET AL., "Synthesis and Pharmacological Characterization of a Potent, Orally Active p38 Kinase Inhibitor" <i>Bioorganic Medical Chemistry Letters</i> 2002, Vol. 12, pp. 1559.	
	C16	DUMAS, J. ET AL., "Discovery of a New Class of p38 Kinase Inhibitors" <i>Bioorg. Med. Chem. Lett.</i> 2000, 10 (18), 2047.	
	C17	EISEN et al., "Phase I trial of BAY 43-9006 (sorafenib) combined with dacarbazine (DTIC) in metastatic melanoma patients," Meeting: <i>2005 ASCO Annual Meeting</i> , Category: Melanoma, Subcategory: Melanoma, Abstract No. 7508	
	C18	EISENHAUER et al., "Impact of new non-cytotoxics in the treatment in ovarian cancer," <i>Int. J. Gynecol. Cancer</i> , 2001, 11 (Suppl. 1), 68-72	
	C19	ESCUJER et al., "Randomized phase III trial of the raf kinase and VEGFR inhibitor sorafenib (BAY 43-9006) in patients with advanced renal cell carcinoma (RCC)," Meeting: <i>2005 ASCO Annual Meeting</i> , Category: Genitourinary Cancer, Subcategory: Kidney Cancer, Abstract No. 4510	
	C20	Facts and Comparisons, 1994, 2703-2705	
	C21	GARCIA-LOPEZ et al., "New routes for the synthesis of pyrrolo[3,2-d]- and -[2,3-d]pyrimidine systems starting from a common pyrrole derivative," <i>Journal of the Chemical Society, Perkin Transactions 1: Organic and Bio-Organic Chemistry</i> (1972-1999) (1978), (5), 483-7	
	C22	HANSON, "Inhibitors of p38 kinase," <i>Expert Opinion on Therapeutic Patents</i> , July 1997, vol. 7, no. 7, pp. 729-733(5)	


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	C23	HEIM et al., "Antitumor effect and potentiation or reduction in cytotoxic drug activity in human colon carcinoma cells by the Raf kinase inhibitor (RKI) BAY 43-9006," <i>International Journal of Clinical Pharmacology and Therapeutics</i> , Vol. 41, No. 12/2003 (616-617)	
	C24	HOTTE ET AL., "BAY 43-9006: early clinical data in patients with advanced solid malignancies" <i>Curr. Pharm. Design</i> 2002, 8(25), 2249-2253.	
	C25	HUBBARD, "Oncogenic mutations in B-Raf: some losses yield gains," Skirball Institute of Biomolecular Medicine and Department of Pharmacology, New York University School of Medicine, New York, NY	
	C26	Internal Medicine, 4 th Edition, 1994, pp. 699-715	
	C27	KEMPTER et al., "Synthese potentieller Pflanzenschutz- und Schädlingsbekämpfungsmittel aus substituierten Anilinen," <i>Pädagogische Hochschule, Eingegangen am 1.7.1982</i> , 101-120	
	C28	KHIRE, U. ET AL., "Omega-Carboxypyrindyl Substituted Ureas as Raf Kinase Inhibitors: SAR of the Amide Substituent" <i>Bioorganic Medical Chemistry Letters</i> , 2004, Vol. 14, pp. 783-786.	
	C29	LEE, J.T., "BAY-43-9006 (Bayer/Onyx). <i>Curr Opin Invest Drugs</i> (2003) 4(6):757-763.	
	C30	LOWINGER, T. B. ET AL., "Discovery of a Novel Class of Potent Raf Kinase inhibitors: Structure Activity Relationships" <i>Clinical Cancer Research</i> 2000, 6(suppl.), 335.	
	C31	LOWINGER, T. B., "Design and Discovery of Small Molecules Targeting Raf-1 Kinase" <i>Curr. Pharm. Design</i> 2002, 8 (25), 2269.	
	C32	LYONS et al., "Discovery of a novel Raf kinase inhibitor," <i>Endocrine-Related Cancer</i> , (2001) 8, 219-225	
	C33	MADWED et al., "Pharmacological Evaluation of BIRB 796, a selective inhibitor of P38 MAP kinase (MAPK), in animal models of endotoxic shock, inflammation and arthritis," <i>Inflammation Res.</i> , 50:S184, 2001	
	C34	MOELLING et al., "Signal transduction as target of gene therapy," <i>Institute of Medical Virology, University of Zürich, Recent Results in Cancer Research</i> , Vol. 142, pp. 63-71	
	C35	MOORE et al., "Phase I study to determine the safety and pharmacokinetics of the novel Raf kinase and VEGFR inhibitor BAY 43-9006, administered for 28 days on/7 days off in patients with advanced, refractory solid tumors," <i>Annals of Oncology</i> , 16:1688-1694, 2005	
	C36	MROSS ET AL., "Drug-drug interaction pharmacokinetic study with the Raf kinase inhibitor (RKI) BAY 43-9006 administered in combination with irinotecan (CPT-11) in patients with solid tumors" <i>International Journal of Clinical Pharmacology Ther.</i> 2003, 41(12), 618-619.	
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	C37	MURPHY et al., "BAY 43-9006 controls tumor growth through inhibition of vascular development," 96 th Annual Meeting, April 16-20, 2005, Anaheim/Orange County, CA	
	C38	NICKEL et al., "Carboxylic acid analogues of suramin, potential filaricides," <i>Indian Journal of Chemistry</i> , Vol. 30B, February 1991, p. 182-187	
	C39	PANKA et al., "BAY 43-9006 induces apoptosis in melanoma cell lines," 96th Annual Meeting, April 16-20, 2005, Anaheim/Orange County, CA	
	C40	WILHELM, S. M. et al., "A Novel Diphenylurea Raf-1 Kinase Inhibitor (RKI) Blocks the Raf/Mek/Erk Pathway in Tumor Cells," <i>Proceedings of the American Association for Cancer Research</i> , March 2001, Vol. 42	
	C41	REDMAN, A. M. ET AL., "P38 Kinase Inhibitors for the Treatment of Arthritis and Osteoporosis: Thienyl, Furyl and Pyrrolyl Ureas" <i>Bioorganic Medical Chemistry Letters</i> , 2001, Vol. 11 No. 1, pp. 9	
	C42	REGAN et al., "Pyrazole urea-based inhibitors of P38 MAP kinase: from lead compound to clinical candidate," <i>J. Med. Chem.</i> 45:2994-3008, 2002	
	C43	RICHLY et al., "Results of a phase I trial of BAY 43-9006 in combination with doxorubicin in patients with primary hepatic cancer," <i>International Journal of Clinical Pharmacology and Therapeutics</i> , Vol. 42, No. 11/204 (650-651)	
	C44	RICHLY, H ET AL., "A Phase I clinical and pharmacokinetic study of the Raf kinase inhibitor (RKI) BAY 43-9006 administered in combination with doxorubicin in patients with solid tumors" <i>Int. Journal Clinical Pharmacology Therapeutics</i> , 2003, Vol. 41, No. 12, pp. 620-621.	
	C45	RIEDL et al., "Potent Raf Kinase Inhibitors from the Diphenylurea Class: Structure Activity Relationships," 2001, <i>Proc. Amer. Assoc. Can. Res.</i> , Vol. 42 No. 923	
	C46	SIU ET AL., "Phase I study of oral Raf-1 kinase inhibitor BAY 43-9006 in combination with gemcitabine in patients with advanced solid tumors" 2003, 39th ASCO meeting, Chicago, IL Abstract 828.	
	C47	SMITH et al., "Discovery of heterocyclic ureas as a new class of raf kinase inhibitors: identification of a second generation lead by a combinatorial chemistry approach." <i>Bioorganic & Medicinal Chemistry Letters</i> , 11 (2001) 2775-2778	
	C48	SORBERA, L.A. ET AL., "Oncolytic Raf kinase inhibitor" <i>Drugs Future</i> 2002, Vol. 27, pp.1141-1147.	
	C49	SPRONSEN ET AL., "Novel treatment strategies in clear-cell metastatic renal cell carcinoma," 2005, <i>Anti-Cancer Drugs</i> , Vol. 16, pp. 709-717	

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	C51	STRUMBERG ET AL., "Results of phase I pharmacokinetic and pharmacodynamic studies of the raf kinase inhibitor BAY 43-9006 in patients with solid tumors," <i>International Journal of Clinical Pharmacology and Therapeutics</i> , 2002, Vol. 40, No. 12, pp. 580-581	
	C52	THAIMATTAM ET AL., "3D-QSAR CoMFA, CoMSIA studies on substituted ureas as Raf-1 kinase inhibitors and its confirmation with structure-based studies," <i>Bioorganic & Medicinal Chemistry</i> , 2004, Vol. 12, pp. 6415-6425	
	C53	THOMPSON ET AL., "Recent progress in targeting the Raf/MEK/ERK pathway with inhibitors in cancer drug discovery," <i>Current Opinion Pharmacology</i> , Aug 2005, Vol. 5, No. 4, pp. 350-356	
	C54	WAN ET AL., "Mechanism of activation of the RAF-ERK signaling pathway by oncogenic mutations of B-RAF," <i>Cell</i> , 2004, Vol. 116, pp. 855-867	
	C55	HANNO ET AL., "Substructure #1," pp/ 1-107, 1996	
	C56	WILHELM, S. M ET AL., "BAY 43-9006 exhibits broad spectrum oral antitumor activity and targets the RAF/MEK/ERK pathway and receptor tyrosine kinases involved in tumor progression and angiogenesis" <i>Cancer Res.</i> 2004, 64(19), 7099-7109.	
	C57	Wilson, Keith et al., "The structural basis for the specificity of pyrimidinylimidazole inhibitors of p38 MAP Kinase" XP-002103155	
	C58	Wisaner et al., "Analogues of platelet activating factor. 7. Bis-aryl amide and bis-aryl urea receptor antagonists of PAF," <i>J. Med. Chem.</i> , 1992, 35, 4779-4789	
	C59	Wright et al., "Clinical trials referral resource. Current clinical trials of BAY 43-9006, Part 1," <i>Oncology</i> , 2005 Apr, 19(4):499-502	
	C60	GEIGER, T. ET AL., "Antitumor Activity of a C-raf Antisense Oligonucleotide in Combination with Standard Chemotherapeutic Agents against Various Human Tumors Transplanted Subcutaneously into Nude Mice", July 1997, Vol. 3, p.1179-1185	
	C61	HANSON, G. J. ET AL., "Pulmonary-Allergy, Dermatology, Gastrointestinal & Arthritis",	

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			Filing Date	December 22, 1998
			First Named Inventor	Scott Miller
			Group Art Unit	1621
			Examiner Name	Kumar, Shailendra
(use as many sheets as necessary)			Attorney Docket Number	BAYER-0006-P01
Sheet	7	of	7	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	C62	CUNNINGHAM, C. C. ET AL., "A Phase I Trial of H-ras Antisense Oligonucleotide ISIS 2503 Administered as a Continuous Intravenous Infusion in Patients with Advanced Carcinoma", 2001 American Cancer Society, Volume 92, Number 5, pages 1265-1271.	
	C63	IWADATE, Y. ET AL., "Intra-arterial ACNU, CDDP chemotherapy for brain metastases from lung cancer: comparison of cases with and without intra-arterial mannitol infusion, <i>Neurol. Surg.</i> , (1993) Vol. 21, No. 6, pp. 513-518	
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